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EXAMINER	
OSTRUP, CLINTON T	

ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,160	PETERSEN ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 October 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the Amendment filed 8/12/08. As directed by the amendment, claims 2-17, 19-26 and 28-30 have been amended. Thus, claims 1-26 and 28-30 are pending in this application are currently pending in this application as claim 27 was cancelled in the preliminary amendment filed October 11, 2005.

Specification

2. The disclosure is objected to because of the following informalities: The numerical reference characters in the specification used to designate specific parts in the drawings are inconsistent. For example, on page 14, line 27, reference character "4" has been used to designate "passages"; however, reference character "4" has previously bee used to designate "the top face" on page 10, line 12.

Appropriate correction is required.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "passages" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Brain (4,241,956).

Brain discloses a laryngeal mask (figures 10-12) comprising at least one airway tube (11) and a mask portion (10), which mask portion (10) comprises a top face (13) and a bottom face (opposite from top face), said bottom face comprising a lumen (14) that communicates with the tube (11) interior, and said top face (13) comprising a closed transition face, said mask portion (10) being at least on the bottom face in the periphery delimited by an inflatable cuff (18), wherein the cuff (18) of the mask portion

comprises inflatable means 21 for abutment against a wall of a pharynx opposite a laryngeal opening for providing a tight connection of the mask portion and the laryngeal opening; and passages are formed between these abutment means and the top face of the mask portion. See: col. 8, line 28 – col. 10, line 42 and figures 10-12.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-10 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins (EP 1219316 A2) in view of Pagan (6,604,525).

Regarding claim 1, Collins discloses a laryngeal mask (see figure) comprising an airway tube (1) having a lumen (hole in tube); and a mask portion (2), said mask portion (3) comprising an inflatable cuff (21); and an intermediary portion (20) forming a transition from said airway tube (1) to said inflatable cuff (21), wherein the airway tube (1) and the intermediary portion (20) are integrally molded, and the inflatable cuff (21) has a first peripheral edge integrally with said intermediary portion (where 25 forms the peripheral edge to where the cuff is attached) a second peripheral edge (where 26 forms the edge where the cuff is attached) connected to said intermediary portion by a joint (adhesive forming connection). Collins teaches all the limitations of instant claim 1 except the inflatable cuff with a first peripheral edge integrally molded with said intermediary portion. See: page 1, [0001]-[0012], figure and abstract.

Pagan teaches integrally forming a mount and a cuff member of a laryngeal mask. See: col. 1, line 35 - col. 3, line 47 and figures 1-9.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the laryngeal mask disclosed by Collins by integrally forming a cuff to a mount, as taught by Pagan to obtain a one piece, integrally formed laryngeal mask that eliminates the time consuming gluing of a cuff and the possibility of a faulty bonded cuff.

Regarding claims 2-8, Collins discloses that the cuff is a thin flexible plastic material and that by molding the tube and mount together enables the wall thickness or shape to be varied, if desired, at different points along the tube. Thus, modifications of the tube thickness are clearly taught by the reference and the mere modification of a tube size is within the skill of those in the art.

Regarding claim 9, the combined references teach a rigid tubing (10) in extension of the airway tube which is completely or partially enclosed by an outer jacket (12) configured as an integral part of the airway tube. See: Pagan, figure 1.

Regarding claim 10, Collins discloses a groove in the airway tube and since the combined references teach the rigid tube as an integral part of the airway tube, it would have been obvious to extend the groove through the entire length of the tube, thus, including the rigid tube. See: Collins, page 1, [0006] and figure 1.

Regarding claim 12, Collins teaches an integrally formed mount and tube made by injection molding. See: Collins, page 2 [0013].

Regarding claim 13, Pagan teaches surface formations in the form of ribs, or the like, as epiglottis glides. See: col. 2, lines 62-65. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified shape of the epiglottis guides into more round bead like structures to perform the same function.

8. Claims 11 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins (EP 1219316 A2) in view of Pagan (6,604,525), as applied to claim 1 above and further in view of Brain (2003/0037790).

The combined references teach all the limitations of claim 11 except the reinforcing ribs that are integral with the airway tube and axially parallel with the central axis of the airway tube.

Brain teaches a laryngeal mask with an airway tube that has reinforcing ribs that are integral with the airway tube and axially parallel with the central axis of the airway tube. See: page 10, [0156] and figures 10B, 10C, 10E, 37D, 48B, 48D, and 49B.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the airway way tube disclosed by the combined references by adding reinforcing ribs as taught by Brain to obtain an airway tube with a better fit to the anatomical airway than cylindrical tubes.

Regarding claims 14-15, Brain teaches a mask portion with two additional inflatable bellows on the top face of the mask. See: Brain, page 18, [0211]-0213] and figures 28-29.

Regarding claim 16, it is common knowledge in the art to apply a water soluble lubricant to an object prior to inserting it into a patient's orifice. Water soluble lubricants allows for easier, less intrusive insertion of objects into patient's orifices and it would have been obvious at the time the invention was made to one having ordinary skill in the art to apply a lubricant prior to a laryngeal mask prior to inserting it into a patient's airway.

Regarding claim 17, Brain teaches a reinforced transition face comprising reinforcing ribs. See: figures 10F, 10G, 48 D, and 49B.

9. Claims 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins (EP 1219316 A2) in view of Pagan (6,604,525), and further in view of Hicks et al., (GB 2367525 A).

Regarding claim 18, the combined references teach a method of manufacturing a laryngeal mask with an airway tube having a lumen; and a mask portion, said mask portion comprising an inflatable cuff (9); and an intermediary portion forming a transition (8) from said airway tube (2) to said inflatable cuff (9), and teach that the mask portion and airway tube made by injection molding.

However, the combined references lack the injection molding process comprising injection molding of the airway tube, the intermediary portion and the cuff having an annularly extending opening between a second peripheral edge of said cuff and said intermediary portion integrally in a closed mould part in a first step, ejecting the airway tube, the intermediary portion and the cuff having the annularly extending opening from the mould in a second step, and providing a closed inflatable cuff by closing of the

annularly extending opening by assembling the second peripheral edge with said intermediary portion by a joint.

Hicks teaches a method of injection molding a face mask in a two step method wherein the mask is formed in the first step and a cushion is formed in a second step. See: page 3, third full paragraph - the end of page 4; figures 1-5 and abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have formed the mount and tube in one injection molding step as disclosed by Collins and then formed a cuff around the mount as disclosed by Pagan in a two step injection molding process as taught by Hicks to obtain a one piece laryngeal mask using a two step injection molding process.

Regarding claim 19, it appears that Pagan teaches the distance between the second peripheral edge and the intermediary position at the annularly extending opening as 1-8 mm, however, if the size is somewhat greater than 1-8 mm, mere modifications of sizes are design characteristics that are well within the skill of those having ordinary skill in the art.

Regarding claim 20, the Hicks reference teaches a method wherein a liquid polymer material is injected into a closed mould at a first pressure and a first temperature, wherein the mould comprises at least one core for providing the inner cavity in a tube (3) and mask portions (13), wherein the mould also comprises two first mould parts, an upper first mould part (5) and a lower first mould part (4), whose interfaces comprise a first interface (forming 13) that is situated in the area corresponding to a lower face of the mask and movable perpendicular to each other's

interface; and wherein the mould also comprises two further second mould parts (forming 9).

However, Hicks does not specifically describe a second movement pattern that is perpendicular to the movement line of the first mould part; the lower first mould part is moved away from the upper mould part; the two second mould parts are moved away from each other by use of second movement pattern; the core is subsequently moved in the same direction as the lower first mould part; and the mask then being finished by ejection from the mould and closing of the annularly extending opening.
Due to the size and shape of a laryngeal tube, it would necessarily be formed by a different sized and shaped mold as compared to that of Hicks. However, Hicks was used to show that an injection mold process is capable of forming both a mask and a patient interface. Since, the combined references teach that a laryngeal airway tube, mount, and cuff can be formed by molding plastics, and Hicks teaches using injection molding to form a mask and a patient interface, the mere designing of a mold for the laryngeal mask is well within the skill of one in the art. Thus, the perpendicular movement and rough core surfaces, as claimed are merely obvious design characteristic of the two step molding process.

Regarding claim 22, the combined references teach a the periphery of the mask portion is formed by an upper and a lower periphery configured by a tongue/groove arrangement, also known as a male/female arrangement, that is subsequently assembled against each other, for providing an essentially closed peripheral cuff. See: Hicks figures 2-5.

Regarding claim 23, the combined references teach a method wherein rigid tubing is arranged in extension of the airway tubing to the effect that an outer jacket configured as an integral part of the airway completely or partially encloses the outer faces of the rigid tubing. See: Pagan figure 1.

Regarding claim 24, the combined references teach a method wherein the airway tube and the mask portion are molded around the rigid tubing. See: Collins, col. 1 [0005] and Pagan col. 3, lines 34-39 and figure 1.

Regarding claim 25, the combined references teach a method wherein the airway tube, the mask portion and the rigid tubing are manufactured from the same polymer material. See: Pagan col. 1, lines 38-48.

Regarding claim 26 the combined references teach a method wherein a tube is subsequently mounted on the peripheral cuff of the laryngeal mask, which tube is at the other end provided with a valve and pilot balloon. See: Collins, col. 2, [0011].

10. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brain (5,241,956) in view of Brain (2003/0037790).

Brain '956 discloses all the limitations of claim 29 except the cuff of the mask potion having at least two inflatable lateral bellows that are arranged on the top face of the mask and symmetrical about a longitudinal axis of the cuff. See: figures 28 & 29.

Brain '790 teaches two inflatable lateral bellows that are arranged on the top face of the mask and symmetrical about a longitudinal axis of the cuff.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the laryngeal mask of Brain '956 by using the two

inflatable lateral bellows, as taught by Brain '790 to obtain a laryngeal mask that provides a symmetrical cushioned support to the back wall of the patient's pharynx.

11. Claim 30 as rejected under 35 U.S.C. 103(a) as being unpatentable over Collins (EP 1219316 A2) in view of Pagan (6,604,525), as applied to claim 1 above and further in view of Cook (6,422,239).

The combined references teach all the limitations of claim 30, except the cuff with reinforced sections foremost on a top face of the cuff.

Cook teaches a laryngeal mask with a cuff that has reinforced sections on the top face of the cuff. See: col. 5, line 54 – col. 6, line 12 and figure 4.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the laryngeal mask disclosed by the combined references by using raised runners as taught by Cook to form a cuff that help guide the laryngeal mask and help prevent lateral movement once the tube laryngeal mask is positioned in the body.

Response to Arguments

12. Applicant's arguments filed August 12, 2008 have been fully considered but they are not persuasive.

13. Regarding applicant's argument to the rejection of claim 28, under 35 U.S.C. 102(b) as being anticipated by Brain (4,241,956), has not been found convincing.

Applicant argues that it would not be correct to say that Brain '956 has a first cuff which comprises a second cuff. First, claim 28 does not require a first cuff which

comprises a second cuff. Claim 28 merely requires "an inflatable cuff (9'), wherein the cuff (9') of the mask portion (3') comprises inflatable means for abutment against a wall of a pharynx opposite a laryngeal opening for providing a tight connection of the mask portion and the laryngeal opening." Brain '956 discloses an inflatable cuff (18) and discloses the same pressure of inflation air via 19 thus simultaneously serves ring 18 and cuff 50." See: col. 8, lines 47-49. Thus, Brain '956 clearly discloses an inflatable cuff that comprises inflatable means for abutment against a wall of a pharynx opposite a laryngeal opening for providing a tight connection of the mask portion and the laryngeal opening, as claimed.

Regarding applicant's argument that it is "not possible to provide a passage between the top face of the mask and the second cuff, since the two elements are directly attached together", has not been found convincing. As shown in figures 10 & 12 of Brain '956, there is a passage between the inflatable ring/cuff (18), the top face of the mask (13), and the inflatable cuff (50). Thus, passages are formed between these abutment means and the top face of the mask, as claimed.

14. Applicant's argument to the rejection of claims 1-10 and 12-13, under 35 U.S.C. 103(a) as being unpatentable over Collins (EP 1219316 A2) in view of Pagan (6,604,525), has not been found convincing.

15. Applicant argues that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a mask where the airway tube and the cuff part were made from the same material) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification,

limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

16. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In the instant case, Collins teaches a tube and mount integrally formed together, by injection moulding from polyurethane, and specifically discloses PVC as being a useful material. Pagan teaches an integrally formed mount and cuff member that are preferably formed of the same thermoplastic material, and specifically teaches PVC as a useful material.

Thus, the combined references disclose a tube, mount, and cuff all made from PVC and it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the laryngeal mask disclosed by Collins by integrally forming a cuff to a mount, as taught by Pagan to obtain a one piece, integrally formed laryngeal mask that eliminates the time consuming gluing of a cuff and the possibility of a faulty bonded cuff.

17. Regarding claims 11 and 14-17 as being unpatentable over Collins (EP 1219316 A2) in view of Pagan (6,604,525) and further in view of Brain (2003/0037790), it appears applicant is relying on their argument against the combination of Collins and Pagan to be applied to the combination of Collins, Pagan, and Brain (2003/0037790).

However, these arguments have not been found convincing, for the reasons set forth above. Thus, this rejection has been maintained for the reasons set forth above.

Applicant's arguments to the rejection of claims 18-26 as being rejected under 35 U.S.C. 103(a) as being unpatentable over Collins (EP 1219316 A2) in view of Pagan (6,604,525), and further in view of Hicks et al., (GB 2367525 A) have not been found convincing.

Applicant argues that claim 18 requires injection moulding of the airway tube, the intermediary portion as well as the cuff portion, whereas Collins discloses an airway tube and intermediary portion are formed in a first step and the cuff is added in a second step; Pagan teaches an intermediary portion is injection moulded in a first step, the cuff is blow moulded in a second step and the airway tube is attached in a third step; and Hicks teaches an intermediary portion is moulded in a first step, the material for the cuff portion is injected in a second step, the cuff portion is inflated in a third step and the airway tube is added in a fourth step. Therefore, applicant argues that it is not clear how a person of ordinary skill in the art would arrive at a method according to the claim 18 where the airway tube, the intermediary portion and the cuff portion are all injection moulded in a single step.

Applicant is reminded that claim 18 does not require a one-step, one-time, single injection mould to form the airway tube, the intermediary portion and the cuff portion. The examiner has considered the formation of the three components as a first step, which has a sub-step of attaching the cuff in a sub-step. However, since Collins discloses a single injection to form a tube and a mount from PVC, and Pagan teaches a

mount and cuff formed of PVC, it would be obvious to one having ordinary skill in the art, at the time the invention was made, to form a single mould that would form the combined elements into a single mould in order to reduce the time and increase the efficiency of forming the laryngeal masks.

18. Applicant's arguments to the rejection of claim 29, as being unpatentable under 35 U.S.C. 103(a) over Brain (5,241,956) in view of Brain (2003/0037790), have not been found convincing.

Applicant argues that there is no direct connation between the lateral bellows 31 and an inflatable cuff, as the lateral bellows 31 are actually part of a foil sheet that is described as a cushion meant to provide pressure against the back surface of a user's throat. In response, the examiner reminds applicant that Brain 2003/0037790 was merely used to provide two inflatable lateral bellows that are arranged on the top surface of the mask and symmetrical about a longitudinal axis. Brain '956 discloses an inflatable cuff that has a direct connection that would inflates the bellow located on the upper surface of a mask. Regarding the passage, a passage would clearly be created on the top of the laryngeal mask between the two bellows (31 of Brain 2003/0037790) and the top face of the mask (13 of Brain '956).

Applicant's arguments to the rejection of claim 30, as being unpatentable under 35 U.S.C. 103(a) over Collins (EP 1219316 A2) in view of Pagan (6,604,525) and further in view of Cook (6,422,239), have not been found convincing.

Applicant argues that there is nothing in Cook that would overcome the deficiencies of the combination of Collins and Pagan; however, applicant is reminded

that Cook was merely used to show the obviousness of placing reinforcement sections on the top face of the cuff as Collins and Pagan disclose a laryngeal mask meeting the limitations of claim 1, as discussed above.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

20. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771